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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,417	11/16/2000	Richard Shimkets	15966-606 (Cura-106)	7720

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/22/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/715,417

Applicant(s)

SHIMKETS ET AL.

Examiner

Richard G Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) N/A.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment of claims 45, cancellation of claims 1, 2, 4, 29 and 32 and the addition of new claims 46-49, Paper No. 18, 2/6/2003, is acknowledged. Claims 44-49 are at issue and are present for examination.

Information Disclosure Statement

The reference C14 of Paper No. 16, filed 2/6/2003, has been considered.

Specification

The disclosure is objected to because of the following informalities:

On page 53, line 28 through page 54, line 3, applicants state that the polypeptide of SEQ ID NO: 32 comprises eleven "Casein kinase II phosphorylation site signature sequences, a [ST]-x(2)-[DE] (Casein kinase II phosphorylation site; SEQ ID NO: 33, and lists **ten** specific sites of SEQ ID NO: 32 where this sequence motif occurs. Inspection of the amino acid sequence of SEQ ID NO: 32 does not show that this motif occurs at any of ten specified sites.

Appropriate correction and/or explanation is required.

Claim Rejection(s) - 35 USC § 101

35 U.S.C. 101 reads as follows:

Art Unit: 1652

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 44-49 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Claims 44-49 are drawn to an isolated polypeptide comprising SEQ ID NO:32 (claim 44), or comprising an amino acid sequence at least 95% identical to SEQ ID NO: 32 wherein said polypeptide has kinase activity (claim 45) and compositions and kits comprising said polypeptides (claims 46-49). Applicants assert that the polypeptide of SEQ ID NO:32 which shares approximately 43% identity with the complement receptor 1 papio hamadryas (GenBank Accession Q29528) and is a member of the serine/threonine kinase family (page 53, lines 24-28 of the instant specification). Applicants further assert that this serine/threonine family can be defined by a polypeptide containing a stretch of highly conserved amino acid residues: "[ST]-x(2)-[DE]" (Casein kinase II phosphorylation site; SEQ ID NO: 33). Applicant's assertion of the function of SEQ ID NO:32 appears to be based solely on sequence similarity as the examiner can find no empirical characterization of the function of a protein having the amino acid sequence of SEQ ID NO:32 in the specification. Further as discussed above applicants assertion of a specific motif, [ST]-x(2)-[DE], within SEQ ID NO: 32 is not at all persuasive with respect to the determination of the function of the claimed polypeptide. One of ordinary skill in the art would recognize that the family of protein kinases is particularly large and members of this family can phosphorylate a broad range of targets. For example, Hanks et al. (*Methods Enzymol* 200:38-62) teach that "eukaryotic

Art Unit: 1652

protein kinases make up an unusually large protein family" (page 38, top) and Hunter (*Methods Enzymol* 200:3-37) teaches that kinases can phosphorylate a wide variety of target amino acids including serine, threonine, tyrosine, histidine, arginine, lysine, cysteine, aspartate, and glutamate (page 3). Hanks et al. further teaches that kinases can even have dual specificity and state that, "this highlights the importance of determining acceptor amino acid specificity directly, rather than relying on sequence similarities" (page 4, left column, middle). Thus, based on the evidence provided by Hanks et al. and Hunter, a skilled artisan would recognize that a disclosure that a particular encoded protein functions as a kinase based solely on sequence similarity to other potential kinases is insufficient to define a "real world" use for the claimed nucleic acids. Furthermore, the examiner knows of no well established utility for an uncharacterized kinase. Regarding applicant's assertion that SEQ ID NO:32 may function as a serine/threonine kinase.

Thus, based on the evidence provided by Hanks et al. and Hunter, an ordinarily skilled artisan would recognize that further research would be required to identify or reasonably confirm a "real world" context of use of the claimed invention. This type of utility is not considered a "substantial utility". See e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966).

For the reasons stated above, the claimed nucleic acids have no specific and substantial utility or a well established utility.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard Hutson', with a long horizontal line extending to the right.

Richard Hutson, Ph.D.
Primary Patent Examiner
Art Unit 1652
April 16, 2003